Risk Management

LIABILITY AND OFF-LABEL PRESCRIPTIONS

Psychiatry (Edgemont) 2009;6(2):43–44

This ongoing column is dedicated to providing information to our readers on managing legal risks associated with medical practice. We invite questions from our readers. The answers are provided by PRMS, Inc. (www.prms.com), a manager of medical professional liability insurance programs with services that include risk management consultation, education and onsite risk management audits, and other resources to healthcare providers to help improve patient outcomes and reduce professional liability risk. The answers published in this column represent those of only one risk management consulting company. Other risk management consulting companies or insurance carriers may provide different advice, and readers should take this into consideration. The information in this column does not constitute legal advice. For legal advice, contact your personal attorney.

QUESTION: I'm concerned about liability for some off-label prescriptions I've written, but I'm confident these are the prescriptions my patient needs. Can I really be sued for giving the right medication just because it's off-label?

ANSWER: Although a lawsuit may be filed following an adverse event, the mere fact that a prescription is off-label does not mean that you will lose. The FDA has stated,[1] and the American Medical Association agrees,[2] that physicians are free to prescribe approved drugs for any scientifically supported use, whether on- or off-label.

The term *off-label* can apply to a wide range of prescriptions, from those that have voluminous support in scientific literature to those that are just now becoming known to the medical community.

Whether a given off-label prescription meets the standard of care will depend on the level of evidence available to support the use and how the clinician used the available evidence. In general, the more scientific evidence there is to support a given off-label use, the more likely that use is to meet the standard of care.

Although a prescription may be considered off-label for any number of reasons, our experience with claims has shown that there are a few particular types of off-label prescriptions that are frequently attacked in litigation following an adverse event.

The first is where the dose is significantly higher than the label recommendation; the second is where the drug is given for an indication not on the label; and the third is where the patient is not part of a population included in the clinical trials listed on the label. This last type usually involves children or geriatric patients.

Whether prescribing on-label or off-label, there are a few guidelines that can help increase patient safety and also reduce your liability risk.

1. KNOW YOUR MEDICINE

This may sound obvious, but it's important to understand, scientifically and clinically, how a given medication is likely to affect your patient. This means staying current with information about the medication. There are many sources of

information, but a few good places to start are the FDA's drug information sheets,[3] treatment guidelines from the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry or other relevant associations, continuing medical education, and peer-reviewed studies.

2. FOCUS ON YOUR PATIENT

This may also sound obvious, but it's equally important. Ask yourself why this particular drug is good for this particular patient at this particular time. If you can't give a clinical or scientific answer, learn more about the drug or the patient, or re-think the treatment recommendation. Also, be sure to discuss treatment options and their risks and benefits with the patient to obtain informed consent.

The process of informed consent is important for all treatments, but off-label treatments may have more risks in the form of unknowns, so adequate time should be allowed for discussing the treatment with your patient.

3. DOCUMENT APPROPRIATELY

We understand that if you wrote a "War & Peace" chart for every patient, you'd never have time to actually treat anyone. The goal should be to document to support adequate continuing care for the patient. Adequate treatment record documentation supports patient care and serves numerous other purposes, including providing the base for a defense in the event of a lawsuit or board complaint. If the documentation supports patient care, it likely will fulfill the purpose of providing a defense.

To adequately support patient care, your treatment record documentation should be such that other clinicians can read your notes and be able to understand what you did in the course of treatment and why you did it. In other words, your decision-making process and basis for clinical recommendations should be clear—the "why" is just as or more important than the "what."

Thoughtful documentation of good clinical care and the informed consent process will discourage many plaintiffs' attorneys from accepting a case. Conversely, poor or no documentation of even the best clinical care can make you an attractive target.

Documenting why you made certain decisions demonstrates thoughtful care and supports the notion that you exercised professional judgment in making your treatment recommendations.

The informed consent process must be documented. When documenting informed consent, the record should reflect your conversations with the patient about the nature of the treatment, the risks and benefits of the treatment, risks and benefits of any other available treatments, the risks and benefits of doing nothing, and the patient's understanding of your discussion.

Documenting the "why" behind your treatment recommendations and the informed consent process is especially important when prescribing off-label because these prescriptions involve at least one factor not supported in the clinical trials leading to FDA labeling. Thoughtful documentation of good clinical care and the informed consent process will discourage many plaintiffs' attorneys from accepting a case. Conversely, poor or no documentation of even the best clinical care can make you an attractive target.

REFERENCES

1. FDA Guidance for Institutional Review Boards and Clinical Investigators. http://www.fda.gov/OC/OHRT/IRBS/offlabel.html. Access date: January 2009.
2. AMA House of Delegates Policy H-120.988
3. US Food and Drug Administration. Index to Drug-Specific Information. http://www.fda.gov/Cder/drug/DrugSafety/DrugIndex.htm. Access date: January 2009.

SUBMIT YOUR OWN QUESTION

To submit a question, e-mail Elizabeth Klumpp, Executive Editor, eklumpp@matrixmedcom.com. Include "Risk Management Column" in the subject line of your e-mail. All chosen questions will be published anonymously. All questions are reviewed by the editors and are selected based upon interest, timeliness, and pertinence, as determined by the editors. There is no guarantee a submitted question will be published or answered. Questions that are not intended for publication by the authors should state this in the e-mail. Published questions are edited and may be shortened.